



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/596,243 | 11/17/2006 | Koji Odan | YAMAP1012US | 4126 |
| 43076 | 7590 | 06/08/2010 | EXAMINER | |
| MARK D. SARALINO (GENERAL) RENNER, OTTO, BOISSELLE & SKLAR, LLP 1621 EUCLID AVENUE, NINETEENTH FLOOR CLEVELAND, OH 44115-2191 | | | HANLEY, SUSAN MARIE | |
| | | ART UNIT | PAPER NUMBER | |
| | | 1651 | | |
| | | MAIL DATE | | DELIVERY MODE |
| | | 06/08/2010 | | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | |
|---|------------------------|---------------------|
| Advisory Action Before the Filing of an Appeal Brief | Application No. | Applicant(s) |
| | 10/596,243 | ODAN ET AL. |
| | Examiner | Art Unit |
| | SUSAN HANLEY | 1651 |

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 26 May 2010 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

a) The period for reply expires _____ months from the mailing date of the final rejection.
 b) The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
 Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
 (a) They raise new issues that would require further consideration and/or search (see NOTE below);
 (b) They raise the issue of new matter (see NOTE below);
 (c) They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 (d) They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
 5. Applicant's reply has overcome the following rejection(s): _____.
 6. Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
 7. For purposes of appeal, the proposed amendment(s): a) will not be entered, or b) will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: _____.

Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
 9. The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
 10. The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See Continuation Sheet.
 12. Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____.
 13. Other: _____.

/Irene Marx/
 Primary Examiner, Art Unit 1651

Continuation of 11. does NOT place the application in condition for allowance because: Claims 1 and 8-11 stand rejected under 35 USC as being unpatentable over Fuji (WO 02/097107) in view of Sasaki et al. (1983), Kim et al. (2002), Wada et al. (JP 200303093090; machine translation) and Taguchi et al. (1994; abstract only).

Applicants argue that one skilled in the art would not consider that the three reactions carried out by Sasaki are conducted in one reaction because a high concentration of phosphate with respect to the cellobiose is used in the second reaction for the purpose of obtaining high efficiency. Applicants submit that if this reaction is used for the third reaction without removing phosphate, the concentration of phosphate is very high due to its release from the G1P. Applicants conclude that phosphate would have to be removed prior to the third reaction. Applicants argue that the yield of the present one pot invention is three times higher compared the step-wise reaction of Sasaki. When glucose oxidase and mutarotase are used the conversion is increased to 54.9%. Applicants assert that the removal of glucose affects the reaction yield by only a 2% increase in Wada. Applicants argue that the extent of the effect of using a one-pot reaction with the removal of glucose could not be predicted over the combination of the prior art since the reaction of cellobiose to G1P becomes a non-equilibrium reaction. Applicants also note that the prior art does not address the problem to be solved, the mechanism to arrive at the solution nor the effects obtained therefrom. Applicants submit that the examiner has used ex post facto analysis and the mere inference and supposition that those skilled in the art would have expected to have succeeded in achieving the claimed method.

Responding to Applicants' argument that the ordinary artisan would not put the three reactions of Sasaki together in one pot due to the alleged build-up of phosphate, the obviousness rejection was not predicated on putting the step-wise reactions taught by Sasaki together in one pot. Fuji was cited to demonstrate that the one pot reaction of sucrose, SP, amylose, phosphate and GP to make chain-extended amylose was known in the art. In the reaction, sucrose and phosphate are reacted to give fructose and G1P and the G1P and GP react to add a glucose monomer to the amylose primer. Sasaki was cited to show that the conversion of cellobiose to glucose and G1P was known in the art. As previously stated, it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute cellobiose and CBP for sucrose and SP in the one-pot reaction system of Fuji since both phosphorylases produce G1P from their respective substrates. The substitution of cellobiose and CBP for sucrose and SP is no more than the predictable substitution of one known element for another for a predictable result. Hence, Applicants' argument regarding the combination of the reactions taught by Sasaki is not relevant to the facts of the rejection.

Responding to Applicants argument regarding the extent of the effect (alleged unexpected results) of the use of a one-pot reaction system using the technique of glucose removal, the reaction conditions used in the specification are not commensurate in scope with the claimed invention. The MPEP states the following:

716.02(d) Unexpected Results Commensurate in Scope With Claimed Invention Whether the unexpected results are the result of unexpectedly improved results or a property not taught by the prior art, the "objective evidence of nonobviousness must be commensurate in scope with the claims which the evidence is offered to support." In other words, the showing of unexpected results must be reviewed to see if the results occur over the entire claimed range. *In re Clemens*, 622 F.2d 1029, 1036, 206 USPQ 289, 296 (CCPA 1980) (Claims were directed to a process for removing corrosion at "elevated temperatures" using a certain ion exchange resin (with the exception of claim 8 which recited a temperature in excess of 100C). Appellant demonstrated unexpected results via comparative tests with the prior art ion exchange resin at 110C and 130C. The court affirmed the rejection of claims 1-7 and 9-10 because the term "elevated temperatures" encompassed temperatures as low as 60C where the prior art ion exchange resin was known to perform well. The rejection of claim 8, directed to a temperature in excess of 100C, was reversed.). See also *In re Peterson*, 315 F.3d 1325, 1329-31, 65 USPQ2d 1379, 1382-85 (Fed. Cir. 2003) (data showing improved alloy strength with the addition of 2% rhenium did not evidence unexpected results for the entire claimed range of about 1-3% rhenium); *In re Grasselli*, 713 F.2d 731, 741, 218 USPQ 769, 777 (Fed. Cir. 1983) (Claims were directed to certain catalysts containing an alkali metal. Evidence presented to rebut an obviousness rejection compared catalysts containing sodium with the prior art. The court held this evidence insufficient to rebut the prima facie case because experiments limited to sodium were not commensurate in scope with the claims.).

In the instant case, it is not established that the alleged unexpected results obtained at a single concentration of each of the reactants is sufficient to support the generic claim which is drawn to any concentration of reactants.

Also, in the instant case, the comparison of the total product yield of latter two reactions by Sasaki and example no. 5-1 of the instant application is not relevant to the rejection because the instant rejection was not predicated on combining the three reactions of Sasaki together in one pot supra. The comparison that should be made is between the yields of the one pot reaction of Fuji (sucrose, SP, amylose, GP and a source of phosphate) and comparable concentrations of substrates in the one-pot reaction of example 5-1 in the instant specification (cellobiose, CBP, amylose, GP and a source of phosphate). Such a comparison would be relevant to see if there is an unexpected result when a one-pot reaction of cellobiose, CBP, amylose, GP and phosphate is carried out.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning (ex post facto), it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Regarding Applicants' motivation for making the invention, the motivation evinced in the prior art does not have to be the same as that stated by Applicants. As previously stated, it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute cellobiose and CBP for sucrose and SP in the one-pot reaction system of Fuji since both phosphorylases produce G1P from their respective substrates. The substitution of cellobiose and CBP for sucrose and SP is no more than the predictable substitution of one known element for another for a predictable result.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUSAN HANLEY whose telephone number is (571)272-2508. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Susan Hanley/
Examiner, Art Unit 1651